

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/724,839
Inventor(s) : Gregory Dean Sunvold *et al.*
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Art Unit : 1623
Examiner : Eric Olson
Docket No. : P-147
Confirmation No. : 2171
Customer No. : 27752
Title : Methods and Kits Related to Administration of a
Fructooligosaccharide

RESPONSE AFTER FINAL OFFICE ACTION

Commissioner for Patents
Via Electronic Filing

This Response is in reply to the Office Action of February 18, 2010, made Final. Please consider the following Remarks and reconsider the application. A Request for Continued Examination is included with this Response. The Director is hereby authorized to charge all required fees (including any extension of time fees) and to credit any overpayments in this and any concurrent or future correspondence to Deposit Account No. 16-2480.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 4 of this paper.

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AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior listings and versions of claims in the application.

Listing of Claims:

Claims 1–31. (Cancelled)

32. (Currently Amended) A method selected from the group consisting of enhancing calcium absorption, improving bone health, improving strength, improving physical activity performance, and combinations thereof, the method comprising administering to a companion animal a companion animal composition comprising from about 0.01% to about 0.2% fructooligosaccharide, by weight of the composition wherein the fructooligosaccharide is a short chain oligofructose comprising from about 30% to about 40% 1-kestose, from about 50% to about 60% nystose, and from about 5% to about 15% 1F-beta-fructofuranosylnystose, by weight of the short chain oligofructose;
wherein the companion animal is selected from the group consisting of dogs, cats, and combinations thereof;
wherein the companion animal composition is a nutritionally balanced kibble comprising from about 20% to about 35% crude protein, from about 10% to about 35% fat, and at least 35% carbohydrate; and
wherein the animal composition comprises a fiber source additional to the fructooligosaccharide, wherein the fiber source comprises beet pulp.

33. (Cancelled)

34. (Previously Presented) The method according to Claim 32 which is selected from the group consisting of enhancing calcium absorption, improving bone health, and combinations thereof.

Claims 35–39. (Cancelled)

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40. (Cancelled)

41. (Cancelled)

42. (Previously Presented) The method according to Claim 34 wherein the companion animal composition is administered at least once daily.

Claims 43–46. (Cancelled)

47. (Previously Presented) The method according to Claim 32 which is a method selected from the group consisting of improving strength, improving physical performance, and combinations thereof.

Claims 48–52. (Cancelled)

53. (Cancelled)

54. (Cancelled)

55. (Previously Presented) The method according to Claim 47 wherein the companion animal composition is administered at least once daily.

Claims 56–63. (Cancelled)

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REMARKS

Claims 32, 34, 42, 47 and 55 are pending in the application. Independent claim 32 has been amended. No new matter has been added. Independent claim 32 now recites:

wherein the companion animal composition is a nutritionally balanced kibble comprising from about 20% to about 35% crude protein, from about 10% to about 35% fat, and at least 35% carbohydrate; and

wherein the animal composition comprises a fiber source additional to the fructooligosaccharide.

Support for these amendments can be found on page 6 of the specification as filed and in the examples describing grains as the remainder of the composition, as described herein below.

Consequently, Applicants respectfully request entry of this amendment and reconsideration of the application.

Rejection Under 35 U.S.C. § 103 Over Heisey

Claims 32-34, 40, 42, 47, 53, and 55 have been rejected under 35 U.S.C. § 103 as being unpatentable over Heisey et al. (US Publication No. 2002/0132780). Applicants respectfully traverse this rejection. However, in an effort to advance prosecution, and without conceding to the basis and/or merit of the rejection, independent claim 32 has been amended. Independent claim 32 now recites, inter alia, wherein the companion animal composition is a nutritionally balanced kibble:

comprising from about 20% to about 35% crude protein, from about 10% to about 35% fat, and at least 35% carbohydrate, and

wherein the animal composition comprises a fiber source additional to the fructooligosaccharide, wherein the fiber source comprises beet pulp.

Thus, for the reasons that follow, Applicants respectfully request reconsideration and withdrawal of the rejection.

Heisey discloses compositions useful for those mammals experiencing painful or debilitating joint, bone, or inflammatory conditions. See para. 35. Such compositions can be directed for use in domestic dogs and domestic cats. See para. 36. Importantly,

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Heisey fails to disclose, teach, or suggest a nutritionally balanced kibble comprised of the ingredients has now amended and does not disclose a fiber source additional to the fructooligosaccharide. As now amended, the composition comprises, inter alia:

from about 20% to about 35% crude protein, from about 10% to about 35% fat, and at least 35% carbohydrate, and

wherein the animal composition comprises a fiber source additional to the fructooligosaccharide, wherein the fiber source comprises beet pulp.

Even more, Heisey specifically teaches compositions that are low in carbohydrate content. See para. 45. The amounts of carbohydrate that Heisey discloses amount to at most 19 grams of carbohydrates per every 230 milliliters of the composition, which, as best understood by Applicants, amounts to about 8% carbohydrate (19/230). As now amended, independent claim 32 recites at least about 35% carbohydrate. Additionally, Heisey is silent regarding fat and/or protein.

Accordingly, Applicants submit that Heisey cannot support a 103 rejection since Heisey teaches low carbohydrate compositions suitable for mammals at risk of diabetes. The carbohydrate level of 35% as now amended in independent claim 32 is clearly different from the disclosure of Heisey. Respectfully, Applicants submit that an 8% amount of carbohydrate and, as best understood by Applicants, the lack of specific disclosure of fat and/or protein as now amended cannot said to obviate the claims of the present application. In sum, Heisey fails to disclose the requisite composition of what one of ordinary skill in the art would consider to be a nutritionally balanced kibble for a dog or cat.

Additionally, as now amended, independent claim 32 recites beet pulp as an additional fiber source. Heisey fails to teach, disclose, or suggest using beet pulp as an additional fiber source. For this additional reason, the rejection should be withdrawn.

However, the Office Action has attempted to remedy the deficiencies of Heisey by combining it with Bui. Applicants submit that such a rejection is incorrect.

First, the combination is not proper. Heisey is related to treatment of joint dysfunction, bone dysfunction, and/or inflammation with compositions comprising particular chondroprotective agents and sweetening agents, such as FOS. Bui is related to

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a weight management pet food that can have 35% to 70% protein, 4% to 10% fat, 5% to 25% fiber, 10% to 35% digestible carbohydrate, and 0.1% to 1% functional ingredient. Accordingly, they are disclosing remedies for completely different health issues that do not overlap. It is not clear why one of ordinary skill in the art treating health issues related to joints, bones, and inflammation, as in Heisey, would look to the weight management pet food, as disclosed in Bui, for any particular purpose. Additionally, it is not clear why one of ordinary skill in the art would select the particular fat, carbohydrate, and protein amounts from a weight management dry pet food of Bui and apply them to a joint/bone/inflammation composition as disclosed by Heisey.

These inapposite teachings are supported by the specifications of each reference. Heisey teaches low levels of carbohydrate, namely less than 8%, while Bui discloses levels of carbohydrate from 10% to 35%. Heisey teaches primarily beverage type compositions but does mention food compositions, including chews, candies, gum, and other confectionary products. Bui discloses dry pet food in the relevant portion of its disclosure. Thus, it is not clear that one of ordinary skill in the art treating joint, bone, and inflammation health with beverage type compositions and food compositions like chews, candies, gum, and other confectionary products would look to dry pet food products for weight management that have higher carbohydrate levels, protein levels at 35% to 70%, and fat levels at 4% to 10%. Accordingly, the combination of these references is not proper for these reasons. Reconsideration and withdrawal of the rejection are respectfully requested for at least this reason.

Second, the combination does not obviate the claims as now amended. The claims as now amended recite beet pulp as an additional fiber source. As best understood by Applicants, the references of record are silent with respect to beet pulp. Accordingly, the rejection should be withdrawn for this additional reason.

Additionally, Applicants also submit that Heisey actually teaches away by disclosing an upper limit on the carbohydrate content of the composition. Consistent with a proper 103 analysis, the invention as whole must be considered. Applicants submit that Heisey's much lower carbohydrate content and the specific teaching to have low

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carbohydrate contents teaches away from the claims of the present application that now recite wherein the companion animal composition is a nutritionally balanced kibble.

In sum, Heisey and Bui are not properly combinable, even if combined, fail to disclose, teach, or suggest all of the elements of the presently pending claims, and also teach away from the presently pending claims as described above. Since the dependent claims necessary include the limitations of independent claim 32, the reasons above particularly apply to those claims as well. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 U.S.C. § 103 Over Anantharaman in view of Kaplan

Claims 32-34, 40, 42, 47, 53, and 55 have been rejected under 35 U.S.C. § 103 as being unpatentable over Anantharaman et al. (US Patent No. 5,952,033) in view of Kaplan et al. Applicants respectfully traverse this rejection because a prima facie case of obviousness has not been made. Applicants further submit that the amendment to independent claim 32 even more fully defines the presently pending claims over the references of record.

As now amended, independent claim 32 recites, inter alia,
wherein the companion animal composition is a nutritionally balanced kibble comprising from about 20% to about 35% crude protein, from about 10% to about 35% fat, and at least 35% carbohydrate; and
wherein the animal composition comprises a fiber source additional to the fructooligosaccharide, wherein the fiber source comprises beet pulp.

Applicants submit that the requisite nutritional elements of protein, fat, and carbohydrate are not properly disclosed, taught, or suggested in Anantharaman and Kaplan. Applicants submit that the fiber source additional to the FOS, wherein the fiber source comprises beet pulp, is also not properly disclosed, taught, or suggested in Anantharaman and Kaplan. For these reasons alone, Applicants respectfully request reconsideration and withdrawal of the rejection.

Applicants also submit that the alleged combination defeats the purpose of Anantharaman. Anantharaman describes adding a natural plant material that is a source

of inulin to the usual ingredients of gelatinized cereal products and then gelatinizing the ingredients so as not adversely affect the palatability of the food. As described previously, Anantharaman discloses a gelatinized cereal product that includes at least about 0.04% kestose, 0.04% nystose, and 0.04% fructosyl-nystose, thus equal amounts of the FOS components. Kaplan discloses a commercial FOS mixture containing three FOS species, GF2 (32.0%), GF3 (53.6%), and GF4 (9.8%). Thus, looking to the amounts of the FOS disclosed by Anantharaman, it discloses equal, corresponding amounts of the FOS composition components, namely 0.04% of each component. However, Kaplan discloses an approximate ratio of 3:5:1 of the components GF2:GF3:GF4. More particularly, Kaplan discloses a ratio of GF2: GF3 of 3:5, a ratio of GF3:GF4 of 5:1, and a ratio of GF2:GF4 of 3:1. That is, each ratio is substantially different than being equal, as discloses in Anantharaman. Specifically, five times more GF3 than GF4, three times more GF2 than GF4, and $1 \frac{2}{3}$ more GF3 than GF3, while Anantharaman discloses equal amounts of GF3 and GF4 and GF5. Thus, Kaplan teaches away from the equal amounts as disclosed in Anantharaman for its specific purpose of not adversely affecting palatability. Accordingly, the alleged combination, while teaching away, defeats the intended purpose of Anantharaman, and such a combination is improper. Reconsideration and withdrawal based on this additional reason are respectfully requested.

Additionally, Applicants additional reiterate their prior position below.

Anantharaman discloses a gelatinized cereal product that includes at least about 0.04% kestose, 0.04% nystose, and 0.04% fructosyl-nystose. Kaplan discloses a commercial FOS mixture containing three FOS species, GF2 (32.0%), GF3 (53.6%), and GF4 (9.8%). Page 2682, right column, second paragraph. Thus, looking to the amounts of the FOS disclosed by Anantharaman, it discloses equal, corresponding amounts of the FOS composition components, namely 0.04% of each component. However, Kaplan discloses an approximate ratio of 3:5:1 of the components GF2:GF3:GF4. More particularly, Kaplan discloses a ratio of GF2: GF3 of 3:5, a ratio of GF3:GF4 of 5:1, and a ratio of GF2:GF4 of 3:1. That is, each ratio is substantially different than being equal, as discloses in Anantharaman. Specifically, five times more GF3 than GF4, three times

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more GF2 than GF4, and $1\frac{2}{3}$ more GF3 than GF3, while Anantharaman discloses equal amounts of GF3 and GF4 and GF5. Such disclosure of clearly different and substantially different ratios of FOS compositions in Anantharaman and Kaplan forms a clear lack of suggestion to combine the references and a clear teaching away of the relative amounts of the FOS components to use.

Moreover, Applicants submit that the references teach away from each other. Anantharaman teaches a FOS composition with similar amounts of FOS components for the effect of decreasing fecal volume, while Kaplan teaches substantially differing amounts of FOS components for the effect of supporting growth of Probiotics. Thus, these amounts are not only substantially different from each other, but the benefits are different. Consequently, Applicants submit that an improper combination of references has been made. Thus, Applicants submit that the conclusion of obviousness is incorrect and that a prima facie case of obviousness has not been made. Reconsideration is respectfully requested.

Moreover, as best understood by Applicants, both Anantharaman and Kaplan are completely silent regarding the methods of enhancing as recited in the present claims. Anantharaman discloses a method of decreasing fecal volume of a pet. See column 3, lines 12-17. Kaplan discloses that FOS mixtures can support the growth of various Probiotics. See Kaplan generally. However, neither Anantharaman nor Kaplan disclose whatsoever a method of enhancing calcium absorption, improving bone health, improving strength, and improving physical activity performance. Consequently, Anantharaman and Kaplan, alone and even when combined, fail to disclose each and every element of the present claims. Consistent with a proper 103 analysis, all of the limitations of a claim must be considered, which has not been done here. Consequently, for this additional reason, Applicants submit that the combination of Anantharaman and Kaplan fail to obviate the present claims since a prima facie case of obviousness has not been made.

Applicants respectfully request reconsideration and withdrawal of the rejection.

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CONCLUSION

This Response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied references. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,
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